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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,182	06/08/2006	Hakan Larsson	1103326-0909	8932

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PATENT DEPARTMENT
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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

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11/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,182	LARSSON ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5* is/are rejected.

7)☐ Claim(s) *7 and 8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/20/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

An Amendment filed August 20, 2007 is acknowledged. Claim 6 is canceled. Claims 5, 7 and 8 remain under consideration.

A brief description of Figure 1 on page 4 of the specification is noted.

An Abstract on a separate sheet of paper is further noted.

An Information Disclosure Statement filed August 20, 2007 is further acknowledged and has been reviewed.

Claims 5, 7 and 8 were provisionally rejected in the last Office Action on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-14 of copending Application No. 10/582388. The claims of the co-pending application are drawn to the administration of a metabotropic glutamate receptor 5 antagonist, such as 2-methyl-6-(phenylethynyl)-pyridine, or a pharmaceutically acceptable salt thereof, to treat the functional gastrointestinal disorder irritable bowel syndrome.

The rejection of record on the ground of nonstatutory obviousness-type double patenting is withdrawn because the claims of the co-pending application are drawn to the treatment of irritable bowel syndrome.

In the last Office Action claims 5-8 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claim 5 was drawn to "treatment of a functional gastrointestinal disorder" comprising administering any metabotropic glutamate receptor 5 antagonist. The rejection was based on insufficient written description in the disclosure.

The subject matter presently under consideration is limited to treatment of functional dyspepsia, an art recognized condition without pathologic correlation. However, no metabotropic glutamate receptor 5 antagonist other than 2-methyl-6-(phenylethynyl)-pyridine (MPEP) is discussed in a method of treatment. Under Biological evaluation, pages 5-8 of the specification, in an animal model following MPEP administration, only functional dyspepsia is described.

Applicants argue MPEP 2163(I)(A) *suggests* the claimed invention as a whole *may be* adequately described when there is a "described or art-recognized correlation or relationship between the structure of the invention and its function." In the present case, Applicants urge metabotropic glutamate receptors (mGluR) are G-protein coupled receptors that are involved in the regulation and activity of many synapses in the central nervous system. More specifically, with respect to the claimed mGluR5, Applicants state it is known that this subtype of mGluR is characterized by a structural similarity, i.e., activates phospholipase C and increases neuronal activity.

Applicants' argument has been given careful consideration but is not found persuasive. The rejection of claim 5 is maintained. No description or art-recognized correlation or relationship between the structure of the invention and its function is noted. Applicants have extrapolated involvement in the regulation and activity of many synapses in the central nervous system

to clinical efficacy without presenting a clear showing that a structure:activity relationship exists. In view of the sensitivity of mGluR5 receptors and the unknown and potentially limitless diverse functionalities of antagonists of mGluR5 receptors, the skilled artisan could not "immediately envisage" the claimed methods of treating functional dyspepsia with any antagonist of mGluR5 receptors based on the limited description provided in the disclosure.

Adequate description requires more than a mere statement that various antagonists are part of the invention. *Genetech Inc. vs. Nova Nordisk* states, "[A] patent is not a hunting license. It is not a reward for a search but a compensation for its successful conclusion and 'patent protection' is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" (42 USPQ 2d 1001, Fed. Circuit, 1997).

Claims 7 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

November 1, 2007 Phyllis G. Spivack

1614

PHYLLIS SPIVACK
PRIMARY EXAMINER